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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,397	05/17/2001	Masaaki Goto	FJIN-107	2388

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	15

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,397	GOTO ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 14 is acknowledged. The traversal is on the ground(s) that there is unity of invention based on "the contents of the claims as interpreted in light of the description and drawings" (see page 2 of the response). This is not found persuasive because Applicant asserts that the special technical feature common to Group I and Group II is stanniocalcin. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, at the time of the instant invention, stanniocalcin was known in the art, and therefore, it cannot serve as the special technical feature. Therefore, there is no unity of invention and the claims are properly restricted. Applicant asserts there is no teaching in Olsen et al. that stanniocalcin is useful for treating obesity. However, this is a recitation of intended use, and does not define the composition of stanniocalcin in the instant application from that of the prior art. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the instant application, Applicant may wish to add a statement that the instant application is a 371 or the national stage entry of the earlier filed PCT application.

Information Disclosure Statement

The information disclosure statement filed 16 March 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Documents EP 0 750 626 B1 and JP 9-511140 could not be found. It is not clear if the Examiner is misreading the priority documents which were filed, or if the documents are missing. Applicant should file clean copies which are clearly labeled along with a copy of the PTO-1449, and the references will be considered accordingly.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is not a single paragraph.

Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to *which the claims are directed.*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to a method of treating or preventing obesity by the administration of stanniocalcin. However, the art area of weight control and treatment of obesity is such that one of ordinary skill in the art would not expect that the administration of a compound such as stanniocalcin would be effective for preventing obesity. Weight control is a multi-factorial process in which the body regulates energy balance (see art cited with this Office action). This "control" is governed not only by the body's requirement to regulate energy, but also by a person's own personal desires to eat. Obesity is a condition that is not only physiological (disease related, genetically related, etc.) but is also a psychological condition. A person who is depressed may eat more and thereby, gain weight to the point of being obese. One of ordinary skill in the art would not conclude that the administration of a compound which exhibits adipogenesis inhibitory activity in cell culture would be effective for prevention of obesity. At present, there is no therapeutic method or composition which has been shown to be effective for prevention of obesity. Even extreme surgical methods, such as stomach bi-pass surgery, are not completely effective in prevention or treatment of obesity in an individual who is determined to overeat. The instant specification provides no *in vivo* data on the claimed method, and the *in vitro* method which is exemplified is not established as a predictive model for determining the effectiveness of a compound for treating or preventing obesity.

The body processes a number of different signals in process of maintaining energy balance. Inputs come from the brain, temperature, exertion, blood glucose levels, the GI tract, etc. The body's control center then decides if food is to be ingested. The biological activity of stanniocalcin on adipocytes is but one factor in this very complicated, multi-factorial system in which the body is attempting to maintain its energy balance, which includes maintaining a reserve of energy. This is one of the reasons why weight loss is so difficult and why obesity is such an enormous health issue in the country today. The instant specification provides no evidence that the administration of stanniocalcin is effective for treatment of obesity. One ordinary skill in the art would not find the claimed method enabled because the experimental model which is exemplified in the specification is not predictive of an effective treatment of obesity. Therefore, the invention as a whole is not enabled.

The specification demonstrates that stanniocalcin exhibits adipogenesis inhibitory effect in adipocytes. Method claims directed to this biological activity, which do not recite treatment of obesity, are enabled by the specification as originally filed. An art search in this area has not been conducted since claims of this nature are not present in the instant application at this time.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation animals, and the claim also recites human which is the narrower statement of the range/limitation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on Monday through Thursday, 8:00AM to 2:00PM; voice mail service is available.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud